

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

<b>CEPHALON, INC. and CEPHALON FRANCE,</b>	)	
	)	
Plaintiffs and	)	
Counterclaim Defendants,	)	
v.	)	CIVIL ACTION NO. 09-00954-GMS
	)	
<b>MYLAN PHARMACEUTICALS INC.,</b>	)	
	)	
Defendant and	)	
Counterclaim Plaintiff.	)	

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**REPLY OF CEPHALON, INC. AND CEPHALON FRANCE  
TO DEFENDANT MYLAN PHARMACEUTICALS INC.'S  
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Plaintiffs Cephalon, Inc. and Cephalon France (collectively "Cephalon"), for their Reply to the Answer, Affirmative Defenses, and Counterclaims of Defendant Mylan Pharmaceuticals Inc. ("Mylan's Counterclaims" [D.I. 16]), filed on February 12, 2010, states as follows:

Responding to Mylan Pharmaceuticals Inc.'s ("Mylan") First, Second, Third, Fourth, Fifth, and Sixth Affirmative Defenses, at pages 10 and 11 of Mylan's Counterclaims, Cephalon reasserts and realleges Paragraphs 1 through 45 of its Complaint for Patent Infringement ("Complaint" [D.I. 1]), and denies the allegations of Mylan's Affirmative Defenses.

**THE PARTIES AND ACTS LEADING TO MYLAN'S COUNTERCLAIMS**

1. Responding to Paragraph 1 of Mylan's Counterclaims, Cephalon admits, on information and belief, that Mylan is a corporation organized and existing under the laws of West Virginia, with a headquarters at 781 Chestnut Ridge Road, West Virginia 26504.
2. Cephalon admits the allegations of Paragraph 2 of Mylan's Counterclaims.
3. Cephalon admits the allegations of Paragraph 3 of Mylan's Counterclaims.

## **JURISDICTION AND VENUE**

4. Responding to Paragraph 4 of Mylan's Counterclaims, this paragraph attempts to aver legal conclusions, to which no response is required. To the extent that a response is required, Cephalon does not contest that Mylan's Counterclaims may arise under 35 U.S.C. § 1 *et seq.*; 28 U.S.C. §§ 2201 and 2202; and 21 U.S.C. § 355(j)(5)(C)(i), but denies that Mylan is entitled to any of the relief it seeks.

5. Responding to Paragraph 5 of Mylan's Counterclaims, this paragraph attempts to aver legal conclusions, to which no response is required. To the extent that a response is required, Cephalon does not contest that this Court has subject matter jurisdiction over this matter, but denies that Mylan is entitled to any of the relief it seeks.

6. Responding to Paragraph 6 of Mylan's Counterclaims, this paragraph attempts to aver legal conclusions, to which no response is required. To the extent that a response is required, Cephalon does not contest that this Court has personal jurisdiction over Cephalon, Inc. or Cephalon France for the purposes of Mylan's Counterclaims 1 through 4. Cephalon denies the remaining allegations in this paragraph.

7. Responding to Paragraph 7 of Mylan's Counterclaims, Cephalon admits that venue is proper in this Court for purposes of the present litigation. Cephalon denies the remaining allegations of this paragraph.

## **BACKGROUND**

### **A. FDA Approval of Brand-Name Drugs**

8. Responding to Paragraph 8 of Mylan's Counterclaims, Cephalon admits that the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended,

relates in part to the approval of drug products by the U.S. Food and Drug Administration (“FDA”), and speaks for itself. Cephalon denies the remaining allegations in this paragraph.

9. Responding to Paragraph 9 of Mylan’s Counterclaims, Cephalon admits that 21 U.S.C. § 355 relates in part to the preparation of a New Drug Application (“NDA”), and speaks for itself. Cephalon denies the remaining allegations in this paragraph.

10. Responding to Paragraph 10 of Mylan’s Counterclaims, Cephalon admits that 21 U.S.C. §§ 355(b)(1) & (c)(2) and 21 C.F.R. §§ 314.53(b) & (c)(2) relate in part to the provision of patent information in an NDA, and speak for themselves. Cephalon denies the remaining allegations in this paragraph.

11. Responding to Paragraph 11 of Mylan’s Counterclaims, Cephalon admits that 21 U.S.C. § 355(j)(7)(A)(iii) relates in part to the FDA’s publication of patent information, which the FDA appears to have implemented in a document entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (or “Orange Book”), and speaks for itself. Cephalon denies the remaining allegations in this paragraph.

**B. Generic Competition-Approval of Abbreviated New Drug Applications**

12. Responding to Paragraph 12 of Mylan’s Counterclaims, Cephalon lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12, and therefore denies the allegations of Paragraph 12 of Mylan’s Counterclaims.

13. Responding to Paragraph 13 of Mylan’s Counterclaims, Cephalon admits that the Drug Price Competition and Patent Term Restoration Act (or “Hatch-Waxman Amendments”), as codified at, *inter alia*, 21 U.S.C. § 355 and 35 U.S.C. §§ 156 & 271(e), provide in part for an Abbreviated New Drug Application (“ANDA”), and speaks for itself. Cephalon denies the remaining allegations of this paragraph.

14. Responding to Paragraph 14 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. § 355(j)(4)(F) relates in part to ANDA approval and bioequivalence, and speaks for itself. Cephalon denies the remaining allegations of this paragraph.

15. Responding to Paragraph 15 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. § 355(j)(2)(A)(vii) and 21 C.F.R. § 314.94(a)(12) relate to patent certification, and speak for themselves. Cephalon denies the remaining allegations of this paragraph.

16. Responding to Paragraph 16 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) relates to patent certification, and speaks for itself. Cephalon denies the remaining allegations of this paragraph.

17. Responding to Paragraph 17 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. § 355(j)(2)(B)(i) relates to notification regarding a paragraph IV certification, and speaks for itself. Cephalon denies the remaining allegations of this paragraph.

18. Responding to Paragraph 18 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. § 355(j)(5)(B)(iii) relates in part to patent infringement actions regarding a paragraph IV certification, and speaks for itself. Cephalon denies the remaining allegations of this paragraph.

19. Responding to Paragraph 19 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. § 355(j)(5)(B)(iii) relates in part to patent infringement actions regarding a paragraph IV certification, and speaks for itself. Cephalon denies the remaining allegations of this paragraph.

**C. Mylan Pharmaceuticals' ANDA**

20. Responding to Paragraph 20 of Mylan's Counterclaims, Cephalon admits, on information and belief, that Mylan submitted to the FDA ANDA No. 20-0043 ("Mylan's

ANDA”) for generic armodafinil tablets in dosage strengths of 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg (“Mylan’s proposed ANDA products”), referencing Cephalon’s approved NDA No. 02-1875 (“Cephalon’s NDA”) for Nuvigil®. Cephalon denies the remaining allegations of this paragraph.

21. Responding to Paragraph 21 of Mylan’s Counterclaims, Cephalon admits that U.S. Reissued Patent No. RE37,516 (“the ’516 patent”), U.S. Patent No. 7,132,570 (“the ’570 patent”), and U.S. Patent No. 7,297,346 (“the ’346 patent”) are among the patents listed in the Orange Book in connection with Nuvigil® and/or Cephalon’s NDA. Cephalon also admits that 21 U.S.C. §§ 355(b)(1)-(c)(2) relate in part to the submission of patent information to the FDA, and speak for themselves. Cephalon denies the remaining allegations of this paragraph, and reasserts and realleges Paragraphs 1 through 45 of Cephalon’s Complaint.

22. Responding to Paragraph 22 of Mylan’s Counterclaims, Cephalon admits, on information and belief, that Mylan’s ANDA includes a paragraph IV certification regarding each of the ’516 patent, the ’570 patent, and the ’346 patent, and that Mylan has sought approval of its ANDA before the expiration of those patents. Cephalon denies the remaining allegations of this paragraph.

23. Responding to Paragraph 23, Cephalon admits that, on or about November 3, 2009, Cephalon received a letter (“the Notice Letter”) from Mylan notifying Cephalon that Mylan had filed ANDA No. 20-0043 seeking approval to market Mylan’s generic armodafinil products prior to the expiration of the ’516 patent, the ’570 patent, and the ’346 patent, and that Mylan was providing information to Cephalon pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Cephalon denies the remaining allegations of this paragraph, and specifically denies that Mylan’s Notice Letter provides a legally sufficient basis for establishing the invalidity and/or non-

infringement of the '516 patent, the '570 patent, and/or the '346 patent, and further reasserts and realleges Paragraphs 1 through 45 of Cephalon's Complaint.

**D. The '346 Patent**

24. Responding to Paragraph 24 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. §§ 355(j)(5)(C) & 355(j)(5)(C)(i)(I)(aa)-(cc) relate in part to patent infringement actions, and speak for themselves. Cephalon denies the remaining allegations of this paragraph.

25. Responding to Paragraph 25 of Mylan's Counterclaims, Cephalon admits that on December 11, 2009, Cephalon filed suit in this District against Mylan alleging, *inter alia*, infringement of the '570 patent and '516 patent under 35 U.S.C. § 271(e). Cephalon also admits that its Complaint did not include allegations pertaining to the '346 patent or U.S. Patent No. 4,927,855 ("the '855 patent"). Cephalon further admits, on information and belief, that in its ANDA Mylan filed a paragraph III certification for the '855 patent. Cephalon denies the remaining allegations of this paragraph, and reasserts and realleges Paragraphs 1 through 45 of Cephalon's Complaint.

26. Responding to Paragraph 26 of Mylan's Counterclaims, Cephalon admits that Mylan and Cephalon negotiated and entered into an Offer of Confidential Access to Mylan's ANDA. Cephalon also admits that 21 U.S.C. § 355(i)(5)(C)(i)(III) relates to offers of confidential access, and speaks for itself. Cephalon denies the remaining allegations of this paragraph, and denies that Mylan is entitled to any of the relief it seeks.

27. Responding to Paragraph 27 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. § 355(j)(5)(C) relates in part to declaratory judgment actions, and speaks for itself. This paragraph attempts to aver legal conclusions, to which no response is required, but Cephalon denies that Mylan is entitled to any of the relief it seeks.

**FIRST COUNTERCLAIM**

**(Declaratory Judgment of Non-Infringement of the '516 Patent)**

28. Responding to Paragraph 28 of Mylan's Counterclaims, Cephalon reasserts and realleges Paragraphs 1 through 27 of this Reply to Mylan's Counterclaims and Paragraphs 1 through 32 of Cephalon's Complaint.

29. Cephalon denies the allegations of Paragraph 29 of Mylan's Counterclaims.

30. Cephalon denies the allegations of Paragraph 30 of Mylan's Counterclaims.

**SECOND COUNTERCLAIM**

**(Declaratory Judgment for Delisting of the '516 Patent From the Orange Book)**

31. Responding to Paragraph 31 of Mylan's Counterclaims, Cephalon reasserts and realleges Paragraphs 1 through 30 of this Reply to Mylan's Counterclaims and Paragraphs 1 through 32 of Cephalon's Complaint.

32. Responding to Paragraph 32 of Mylan's Counterclaims, Cephalon admits that 21 U.S.C. 355(j)(5)(C)(ii) relates to counterclaims to patent infringement actions, and speaks for itself. Cephalon denies the remaining allegations of this paragraph, and denies that Mylan is entitled to any of the relief it seeks.

33. Cephalon denies the allegations of Paragraph 33 of Mylan's Counterclaims.

**THIRD COUNTERCLAIM**

**(Declaratory Judgment of Invalidity of the '570 Patent)**

34. Responding to Paragraph 34 of Mylan's Counterclaims, Cephalon reasserts and realleges Paragraphs 1 through 33 of this Reply to Mylan's Counterclaims and Paragraphs 1 through 45 of Cephalon's Complaint.

35. Cephalon denies the allegations of Paragraph 35 of Mylan's Counterclaims.

36. Cephalon denies the allegations of Paragraph 36 of Mylan's Counterclaims.

**FOURTH COUNTERCLAIM**  
**(Declaratory Judgment of Non-Infringement of the '346 Patent)**

37. Responding to Paragraph 37 of Mylan's Counterclaims, Cephalon reasserts and realleges Paragraphs 1 through 36 of this Reply to Mylan's Counterclaims and Paragraphs 1 through 45 of Cephalon's Complaint.

38. Responding to Paragraph 38 of Mylan's Counterclaims, this paragraph attempts to aver legal conclusions, to which no response is required, but Cephalon denies that Mylan is entitled to any of the relief it seeks.

39. Cephalon denies the allegations of Paragraph 39 of Mylan's Counterclaims.

40. Cephalon denies the allegations of Paragraph 40 of Mylan's Counterclaims.

**MYLAN'S PRAYER FOR RELIEF**

41. Responding to Mylan's Prayer for Relief on pages 18 to 19 of its Counterclaims, Cephalon denies that Mylan is entitled to any of the relief sought in Mylan's Prayer for Relief, or any other relief sought in Mylan's Counterclaims.

**DEFENSES**

As an affirmative defense, Cephalon alleges as follows:

**First Defense**

42. Mylan's First, Second, Third, and Fourth Counterclaims fail to state a claim upon which relief can be granted.



**PRAYER FOR RELIEF**

Wherefore, Plaintiffs Cephalon, Inc. and Cephalon France respectfully request that the Court enter judgment against Mylan and that the Court enter an order providing as follows:

- A. Dismissing Mylan's First, Second, Third, and Fourth Counterclaims with prejudice;
- B. Denying Mylan all relief requested by Mylan in its Answer, Affirmative Defenses, and Counterclaims to Cephalon's Complaint;
- C. Entering judgment in favor of Cephalon, Inc. and Cephalon France and granting Cephalon, Inc. and Cephalon France all the relief against Mylan prayed for in its Complaint;
- D. Awarding Cephalon its attorney fees, costs, and expenses in this action; and
- E. Awarding Cephalon any further and additional relief as this Court deems just and proper.

Of Counsel:

Respectfully submitted,

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CEPHALON, INC. and CEPHALON FRANCE

Dated: March 8, 2010

**CERTIFICATE OF SERVICE**

I, hereby certify that on the 8<sup>th</sup> day of March, 2010, I served a true and correct copy of **REPLY OF CEPHALON, INC. and CEPHALON FRANCE TO DEFENDANT MYLAN LABORATORIES, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS** on the counsel of record listed below in the manner indicated:

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